REMARKS/ARGUMENTS

Claims 89 – 112 are pending.

Double – Patenting Rejection

Claims 89-111 are rejected on the group of non-statutory obviousness-type double patenting over claims 1-22 of US Patent No. 7,544,370.

Claims 89-105 and 112 are rejected on the groups of non-statutory obviousness-type double patenting as being unpatentable over claims 1-21 of US Patent No. 7,550,153 and claims 1-7 of US Patent No. 7,553,498.

Applicants are submitting terminal disclaimers herewith.

Rejections under 35 USC 103

The examiner comments that the instant claims do not require the core to be an extruded spheroid core composed of a pantoprazole compound and surfactant and not a seed core. This is not correct. Applicants respectfully point out that *the claims provide for the spheroid core to contain the active component and one or more excipients comprising the groups identified therein.* Further, claims 106 – 111 expressly recite extrusion and spheronization.

The examiner mistakenly comments that the claims do not require a surfactant. *Polysorbate 80 is a surfactant recited in the claims.* It is noted that each of the recited excipients is present in the composition; they are not part of a Markush group. The open claim language permits the presence of additional optional excipients but the excipients comprise each of the recited components in the claims.

The cited prior art does not suggest the pantoprazole multiparticulates having the combination of features provided by the present invention, including the components of the extruded and spheronized core discussed above, the inner seal coat comprising hydroxypropylmethyl cellulose, the enteric coat, all within multiparticulates having an average diameter of about 0.7 mm to about 1.25 mm. As

discussed in the background, a need existed in the art for a formulation which could be used for patients who have difficulty swallowing. However, until the present invention, the art was without any suggestion as to how to provide a multiparticulate formulation which is useful for this purpose and which exhibits suitable stability.

Claims 89-112 are rejected under 35 USC 103(a) as being unpatentable over US 5,753,265 in view of US Patent No. 5,997,903, or in the alternative.

Applicants respectfully traverse this rejection.

The combined teachings of the cited documents fail to suggest the present invention.

The combined teachings of the '265 patent and the '903 patent do not suggest the criticality of the size of the multiparticulates provided by the present invention; nor does these patents recognize any issues associated with preparation of such multiparticulates. There is no suggestion of a multiparticulate having the combination of active components and the amount of surfactant and other recited excipients which are recited in the claimed invention.

The '903 patent describes problems associated with pellets or compressed tablets. The examples show formulations containing significant amounts of a sugar component, which is not present in the claimed invention. There is no teaching of importance of the surfactant in the core, such as is recited in the claims of the present invention. The '265 patent focuses on the problems associated with disruption of a coating layer during the tabletting process which causes degradation of their active component. The '265 patent focuses on the plasticity of the enteric coating layer, and provides for use of a plasticizer to enable their mulit-layer tablet to withstand compression during the tabletting process. As such, the '265 patent does not recognize any of the stability issues associated with multiparticulate formulations of the size provided by the present invention, much less provide solutions to these problems. US 5,753,265 does not teach or suggest a multiparticulate, indicating that the size of their seeds which provide the base of their core is not essential for their

invention [col. 6, lines 47-50]. The '265 patent describes a core which contains a significant amount of sugar in the core [Example 2 – mannitol is 43% of the solids in the core] Example 3 [sugar sphere is 43% of the solids in the core]; Example 10 [sugar sphere 61% of solids in core]; Example 12 [sugar sphere is 61% of solids in core].

In contrast, the present claims do not recite any sugar component in the core; further, even at the lowest percentages of the recited pantoprazole and the combination of excipients recited in the present claims, the composition of the invention would not allow the amount of sugar which is present in the core of the '265 examples or the '903 patent to be in the multiparticulates. The cited patents lack any suggestion of a multiparticulate having a core containing the amount of a surfactant provided by the present invention.

Thus, the combined teachings of the art fail to suggest the combination of elements provided by the present invention.

Reconsideration and withdrawal of the invention is requested.

Claims 89-112 are rejected under 35 USC 103(a) as being unpatentable over US 6,159,499 and US 5,753,265 in view of US 5,997,903.

Applicants respectfully traverse this rejection.

No combination of the '499, '265 or '903 patents suggest the criticality of providing multiparticulates of the size of those of the present invention, or recognizes any issues associated with preparation of multiparticulates of this size. There is no suggestion of a multiparticulate having the combination of active components and the amount of surfactant or the other recited excipients which are recited in the claimed invention.

Both the '499 and '265 patent describe cores which contain significant amounts of a sugar component. There is no recognition of the problems associated with stability of a multiparticulate formulation of the size provided by the claimed

invention. Nor is there any recognition of the importance of a surfactant in the amount provided by the present invention.

US 6,169,499 provides a composition which is substantially free of alkaline – reacting compounds, containing a core with an active which is not in the form of an alkaline salt, an intermediate layer, and an enteric layer. The '499 patent describes cores which contain significant amounts of a sugar. The "microtablets" described therein have a diameter of between 2 and 4 mm [col. 8, lines 45 – 47]. The '265 patent reports that it addresses the problems associated with disruption of a coating layer during the tabletting process by providing for use of a plasticizer to enable their mulit-layer tablet to withstand compression during the tabletting process. The '265 patent does not recognize any of the issues associated with preparation or storage of multiparticulate formulations of the size provided by the present invention, much less provide solutions to these problems. The '265 indicates that the size of their seeds which provide the base of their core is not essential for their invention. Clearly, size is important to the present invention, in order to permit patients who have difficulty swallowing to take the drug. The '903 patent does not add anything to the combination of '499 and '265 to supply the defects thereof. The '903 patent focuses on problems associated with pellets or compressed tablets. The examples show formulations containing significant amounts of a sugar component, much more than can be present in the present compositions. There is no teaching of importance of the surfactant in the core, such as is recited in the claims of the present invention.

For these reasons, applicants request reconsideration and withdrawal of this rejection.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper, or credit any overpayment in any fees, to our Deposit Account, Number 08-3040.

Respectfully submitted
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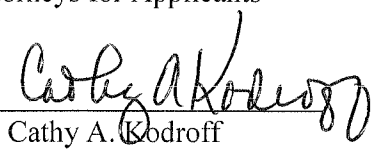
By 

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